K121656
PG. 1 OF 3

SEP 24 2012

510(k) SUMMARY

Gemini Lithotripter

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: September 4, 2012

Device Trade Name

Gemini Lithotripter

Classification Name

Extracorporeal Shock Wave Lithotripters (21 C.F.R. § 876.5990)

Predicate Devices

Dornier Lithotripter (Doli) (P840008, S062)

Dornier Lithotripter 140 (Doli 140) (K011773)

Intended Use / Indications for Use

The Gemini is indicated for the fragmentation of urinary tract stones, i.e., renal calyceal stones, renal pelvic stones, and upper ureteral stones.

Purpose of the Special 510(k) Notice

The Gemini is a modification to Dornier's Lithotripter (P840008, S062) and the Doli 140 (K011773). Specifically, the Gemini is the same device as the cleared predicate Doli products with the exception of the modifications outlined below:

- Minor changes to the patient table, including weight limit, travel range and speed;
- Minor changes to the X-ray system to include an optional larger Image Intensifier and use of an alternate X-ray generator;
- Use of an alternate ultrasound unit; and
- Use of an alternate image storage system.

Technological Characteristics/Principles of Operation

The Gemini is a modular urological work station designed for extracorporeal shock wave lithotripsy ("ESWL") and for diagnostic and therapeutic procedures usual in Urology. The Gemini is composed of the following modules: (1) basic unit with integrated X-ray C-arm and

therapy arm for shockwave treatment; (2) patient table; (3) control desk – user interface; and (4) ultrasound unit.

As indicate above, the Gemini is an extracorporeal shock wave lithotripter used for fragmentation of urinary tract stones, i.e., renal calyceal stones, renal pelvic stones, and upper ureteral stones. The technology to perform this function involves use of an electromagnetic shock wave emitter ("EMSE"). In the case of the subject device and the predicate devices, the identical shock wave source is used. This source, the 140f EMSE, has a well-established record of performance and also is utilized in other Dornier Lithotripers that have been cleared by FDA (e.g., Dornier Compact Alpha (K002929) and Dornier Compact Delta (P840008, S066)).

The other elements of the Gemini, i.e., the patient table and the X-ray unit, are also are similar to that of other cleared stationary Lithotripters, the Doli 140 (K011773) and the Dornier Lithotriper (P840008, S062). They perform the same function and operate in the same manner during the procedures involved in the fragmenting of urological stones.

Performance Data

The company has complied with all of the requirements described in FDA's *Guidance for the Content of Premarket Notifications (510k's) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi.*

Device testing was performed to confirm compliance with the following standards:

o IEC 60601-1:2007	Electrical safety of medical devices
o IEC60601-1-2:2007	Electromagnetic compatibility
o IEC 60601-1-3:2008	Radiation protection
o IEC 60601-1-6:2008	Usability
o IEC 60601-2-7	Safety of high-voltage generators of diagnostic X-ray generator
o IEC 60601-2-28	Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
o IEC 60601-2-36:1997	Extracorporeally induced Lithotripsy
o IEC 60601-2-32:1995	Safety of X-ray equipment
o ISO 13485:2003+AC:2007	Quality management system
o IEC 61846	Ultrasonics – Pressure pulse lithotripters characteristic of fields

In all instances, the Gemini Lithotripter functioned as intended and results observed were as expected.

In addition, the system and its software was tested and validated during the company's design control process and the system met all acceptance criteria. The anti-collision system of the subject device was verified to perform as designed to mitigate the risk of injury. The methodology for accurately locating the stone was tested during the design verification testing and the assessment demonstrated that the system is capable of locating the shock wave focus area with sufficient accuracy. Lastly, the device manual was reviewed and approved as part of the design control process. It contains all necessary warnings, cautions and instructions to mitigate potential injuries.

Substantial Equivalence

The Gemini Lithotripter is as safe and effective as the identified predicate devices listed above. The Gemini Lithotripter has the same intended uses / indications for use, technological characteristics, and principles of operation as its predicate devices. Performance data demonstrate that the Gemini Lithotripter is as safe and effective as the predicate devices. Thus, the Gemini Lithotripter is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 24 2012

Mr. John Hoffer
VP Quality, Regulatory, Clinical
Dornier MedTech America
1155 Roberts Blvd.
KENNESAW GA 30144

Re: K121656
Trade/Device Name: Gemini
Regulation Number: 21 CFR§ 876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: LNS
Dated: September 4, 2012
Received: September 5, 2012

Dear Mr. Hoffer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K121656

Device Name: Gemini

Indications for Use:

The Gemini is indicated for the fragmentation of urinary tract stones, i.e. renal calyceal stones, renal pelvic stones, and upper ureteral stones.

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121656